

Serial No.: 09/581,976
Group Art Unit No.: 1648

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides compositions comprising either an E6 or/and E7 or an E6/E7 fusion protein optionally linked to an immunological fusion partner having T cell epitopes, and adjuvanted with an immunomodulatory CpG containing oligonucleotide. In particular, the present invention relates to vaccines comprising fusions proteins, comprising a protein or part of a protein that provides T helper epitopes (such as protein D from *Haemophilus influenzae* B) and an antigen from a human-papilloma virus (eg comprising an E6 or E7 protein from HPV 16 or 18 strain associated with cancer) that find utility in the treatment or prophylaxis of human papilloma induced tumours, wherein the vaccine is formulated with a CpG containing oligonucleotide as an adjuvant.

Concluded.

IN THE CLAIMS:

~~Please amend claims 1-5, 7-9, and 15-16 as follows:~~

1. (Amended) A composition comprising an E6 or E7 protein or E6/E7 fusion protein from HPV optionally linked to an immunological fusion partner having T helper epitopes, and an immunostimulatory CpG oligonucleotide containing an unmethylated CpG dinucleotide.
2. (Twice Amended) A composition as claimed in claim 1 wherein the fusion partner is selected from the group consisting of: protein D or a fragment thereof having T helper epitopes from *Haemophilus influenzae* B, lipoprotein D or fragment thereof having T helper epitopes from *Haemophilus influenzae* B, NS1 or fragment thereof having T helper epitopes from *Influenzae Virus*, and LYTA or fragment thereof having T helper epitopes from *Streptococcus Pneumoniae*.
3. (Twice Amended) A composition as claimed in claim 1 wherein the E6 or E7 proteins are from HPV16 or HPV18.
4. (Twice Amended) A composition as claimed in claim 1 wherein the E7 protein is mutated to reduce the binding for the retinoblastoma gene product.
5. (Twice Amended) A composition as claimed in claim 1 wherein a mutation is introduced into the E6 protein wherein inactivation of the p53 tumour suppressor protein by E6 is eliminated.

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7. (Twice Amended) A composition as claimed in claim 1 further comprising an additional HPV antigen wherein the additional HPV antigen is one or more antigens selected from the group consisting of E2, E5, L1 and L2.

8. (Twice Amended) A composition as claimed in claim 1 wherein the immunostimulatory CpG oligonucleotide comprises a hexamer motif: purine purine cytosine guanine pyrimidine pyrimidine.

9. (Twice Amended) A composition as claimed in claim 1 wherein the immunostimulatory CpG oligonucleotide has two or more CpG motifs.

15. (Twice Amended) A method of preparing a composition as claimed in claims 1-11 or 16, comprising admixing an E6, E7 or E6/E7 fusion protein optionally linked to an immunological fusion partner having T helper epitopes, and an immunostimulatory CpG oligonucleotide.

16. (Amended) A composition as claimed in claim 6 further comprising an additional HPV antigen wherein the additional HPV antigen is one or more antigens selected from the group consisting of E2, E5, L1 and L2.

Please add the following new claims 17-20:

17. A composition as claimed in claim 7 wherein L1 and L2 are presented together as a virus like particle or wherein L1 alone is presented as a virus like particle or as a capsomere structure.

18. A method of inducing an immune response in a patient to an HPV antigen comprising administering a safe and effective amount of a composition as claimed in claim 17.

19. A method of preventing or treating HPV induced tumours in a patient comprising administering a safe and effective amount of a composition as claimed in claim 17.

20. A method of preparing a composition as claimed in claim 17, comprising admixing an E6, E7 or E6/E7 fusion protein optionally linked to an immunological fusion partner, and an immunostimulatory CpG oligonucleotide.

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